

Registration of a Domestic Drug Establishment in SPL Format

SPL Release Four Training Session – Module 2

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Electronic Registration of Drug Establishments

- Each Registrant (owner/operator firm) must submit one SPL file with registration information for all of its facilities (unlimited amount of domestic or foreign establishments permitted per file)
- Updates of information require re-submission of the same updated SPL file (i.e., same setID; at least annually)
- Simplified SPL files are submitted for 'No Change' or 'Out of Business' notification

Benefits

- Registrant can include all **drug** establishments it owns/operates in one SPL file (replaces need to submit one paper 2656 form for each establishment.)
- Update registration data “instantly” (No FDA data entry required)
- Re-register all establishments annually with one file
- View updated information on Drug Firms Annual Registration Status (DFARS) website.
- Locate DUNS Numbers of manufacturers on DFARS website

Transitioning from Paper to Electronic: Drug Registration and Listing Note

- If you register your drug establishment(s) **electronically**, do not register the same drug establishment(s) using the **paper** (FDA Form 2656)
- Applies to establishment electronically registered (beginning July 2008)

Administrative (Document Tracking Information)

Basic information to identify the SPL document:

- **Document ID:** is a Globally Unique Identifier (GUID) and is unique for each version of the document. Letters used in a GUID are lower case.
- **Document Type:** The `<code>` is the LOINC code which provides information on the document type.
- **Effective Time:** provides a date reference to the SPL version including the year, month and day as yyyyymmdd.
- **SetID:** is a GUID and is a unique identifier for the document that remains **constant** through all versions/revisions of the document.
- **Version number:** is an integer greater than zero that provides a sequence to the versions of the document.

Establishment Registration Data

- **Document Information**

- Type of Document
- ID
- Set ID
- Version Number
- Effective Time

- **Registrant**

- Name
- DUNS Number

- **Registrant Contact**

- Name
- Mailing Address
- City
- State
- Country
- Postal Code
- Telephone Number
- Email Address

Establishment Registration Data (cont...)

- **Establishment**
 - Name
 - DUNS Number
 - FEI
 - Street Address
 - City
 - State
 - Country
 - Postal Code
 - Type of Operation(s)
- **Establishment Contact**
 - Name
 - Mailing Address
 - City
 - State
 - Country
 - Postal Code
 - Telephone Number
 - Email Address

Establishment Registration

SPL Xforms View

HL7 SPL - Establishment Registration v 0.71

Open Save As Save

Establishment Registration Preview

Document Information

Type of Document	ESTABLISHMENT REGISTRATION
ID	4ff69f20-6dc3-49ca-bb3c-0d589ff4c0b1
Set ID	118ec196-50d7-49b2-946a-831d29702818
Version Number	1
Effective Time	20080909

example(YYYYMMDD)

Registrant

Name	Acme, Inc.
DUNS Number	2223334441

Registrant Contact

Name	Deborah Tyler
Mailing Address	222 Bonifant Avenue
City	Fort Washington
State	PA
Country	USA
Postal Code	35295
Telephone Number	tel:+1-800-435-4585
Email Address	mailto:deborah.tyler@acme.com

example(tel:+1-201-555-1212)
example(mailto:xportal@globalsubmit.com)

Establishment Registration

SPL Xforms cont...

Establishment		
Name	Acme Manufacturing, Inc.	
DUNS Number	475859252	
FEI	35295835928	
<input type="button" value="Add FEI"/> <input type="button" value="Delete FEI"/>		
Street Address	777 Sampson Street	
City	Mason	
State	PA	
Country	USA	
Postal Code	35859	
Type of Operation	manufacture ▼	
<input type="button" value="Add Type of Operation"/> <input type="button" value="Delete Type of Operation"/>		
Establishment Contact		
Name	Pam Jamison	
Mailing Address	777 Sampson Street	
City	Mason	
State	PA	
Country	USA	
Postal Code	35859	
Telephone Number	tel:+1-800-778-8359	example(tel:+1-201-555-1212)
Email Address	mailto:pam.jamison@acme.com	example(mailto:xportal@globalsubmit.com)
<input type="button" value="Add US Agent"/> <input type="button" value="Delete US Agent"/>		
<input type="button" value="Add Importer"/> <input type="button" value="Delete Importer"/>		

Establishment Registration SPL Document

Product Information	
Product Type	ESTABLISHMENT REGISTRATION

Registrant - Acme, Inc. (2223334441)			
Contact	Address	Telephone Number	Email Address
Deborah Tyler	Address: 222 Bonifant Avenue City, State, Zip: Fort Washington, PA, 35295 Country: USA	+1-800-435-4585	deborah.tyler@acme.com

Establishment			
Name	Address	ID/FEI	Operations
Acme Manufacturing, Inc.	Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA	475859252	manufacture
Contact	Address	Telephone Number	Email Address
Pam Jamison	Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA	+1-800-778-8359	pam.jamison@acme.com

Electronically Registered Drug Establishments Online

- Example of actual Drug Firms Annual Registration Status Website Display

Pfizer approved use of their data in presentation

Website address: <http://www.fda.gov/cder/dfars/docs/querydrls.htm>

Pfizer Laboratories Div Pfizer Inc	1819598	006059075	100 Pfizer Drive Terre Haute, IN 47802 USA	2008
Pfizer Laboratories Div Pfizer Inc	2410924	134489525	630 Flushing Avenue Brooklyn NY 11206 USA	2008
Pfizer Laboratories Div Pfizer Inc	1211022	148697167	Eastern Point Road Groton, CT 06340 06340	2008

Initial Establishment Registration Submission

- Initial electronic submission for establishments already registered
 - Registrants include information for **all** of their establishments in one *Establishment Registration* SPL file. Each establishment is in only one **ER** SPL file.
 - If establishment is included in another **ER** SPL w/different setID, SPL will FAIL validation

Electronically Requesting an FEI Number

- Request an FEI Number using SPL
 - Include all establishments in one file.
 - Add the FEI numbers for all of the previously registered establishments (registered in paper or electronic format)
 - Include information for new establishment (leave FEI number field empty)
 - Request for FEI will be routed to appropriate FDA team

Correcting an ER SPL with Validation Error

- Correct SPL file validation error
 - If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person. Open the SPL file and correct the errors.
- ***SPL file **never** made it into the FDA eList system***

Correcting Mistake in Valid SPL Just Submitted

- Correct a mistake in an SPL file just submitted
 - Open the SPL file, correct the mistake,
 - Use
 - **new id root**
 - **new version number**
 - **original setId root**
 - appropriate effective time.
- ***SPL file was **valid** and loaded into FDA eList system

Updating an ER SPL

- Update information for an **electronically** registered establishment
- Update anytime during year **or** for annual registration
 - Open the previous SPL file and fill in the new information **without changing the other existing information.**
 - Use
 - new id root
 - new version number
 - original setId root
 - appropriate effective time.

Adding a New Establishment

- Add a new establishment to your ER SPL file:
 - Open the previous SPL file
 - Fill in the information on a new establishment **without changing the information on the other establishments.**
 - Use
 - **new** id root
 - **new** version number
 - **original** setId root
 - appropriate effective time.

Removing an Establishment

- Remove a previously **electronically** registered establishment
 - Open the previous ER SPL file, **without changing the existing information on the other establishments**, and remove the specific establishment information.
 - Use
 - **new** id root
 - **new** version number
 - **original** setId of your ER SPL
 - appropriate effective time.

Establishment Re-Registration No Changes

- Simple process for annually re-registering establishments which have no changes
- Must have already **electronically** registered the establishments once.
- Submit No Change Notification SPL

Establishment Re-Registration

No Changes

- No changes to registration information
 - Each year when the information is updated, if there is no change:
 - Create an SPL file with the *document type* **No change notification** with a **new** id root and **new** version number with the **original** setId and the appropriate effective time.
 - Registrant and establishment information is **not** included with an SPL file with the *document type* **No change notification**.

Establishment

No Change Notification SPL

Product Information	
Product Type	NO CHANGE NOTIFICATION

Revised: 04/2008

Going Out of Business?

- Registrant goes out of business
 - If the registrant goes out of business, create an SPL file with the *document type* **Out of business notification** using a **new** id root and **new** version number with the **original** setId and the appropriate effective time. Registrant and establishment information is not included with an SPL file with the *document type* **Out of business notification**.
 - Applicable for registrants who electronically registered establishments

Establishment Out of Business Notification

Product Information	
Product Type	OUT OF BUSINESS NOTIFICATION

Revised: 09/2008

Certified 2656 Paper Form?

- No certified paper forms for e-registered establishments
- Check DFARS website for electronically registered establishments

Common Errors in Establishment Registration SPL

- Incorrect telephone format
- Wrong e-mail format
- Incorrect ISO-3166 Country Code
- Mismatch for DUNS Number & Establishment name
- Files uploaded to Gateway without a folder

SPL-related Technical Assistance/Questions

- 1:1 Electronic Drug Establishment Registration and Drug Listing Sessions Available
- SPL e-mail account (spl@fda.hhs.gov)

Next Session

- Establishment Registration – International Establishments

Questions

Thank you!